DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

COPY

January 27, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-29

Kam Wong, President
Kamco Seafood, Inc.
5517 Fourth Avenue South
Seattle, Washington 98108

WARNING LETTER

Dear Mr. Wong:

We inspected your firm located at 5517 Fourth Avenue South, Seattle, Washington, on October 5,7, and 12, 1999, and found that you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery products (Seafood HACCP regulations). A FDA 483 form (copy enclosed) listing the deviations was presented to Victor Tang, Manager, at the conclusion of the inspection. These deviations, some of which were previously brought to your attention, cause your fresh Dungeness crab to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's homepage at www.fda.gov.

The deviations were as follows:

1. You must have a HACCP plan that lists the critical control points, to comply with 21 CFR 123.6(c)(2). Your firm's HACCP plan for cooked ready-to-eat Dungeness Crabmeat does not list the critical control point of cooking for controlling the food safety hazard of pathogens.

2. You must have monitoring records which document the actual values and observations obtained during monitoring in order to comply with 21 CFR 123.6(c)(7). Your monitoring record(s) for the cooking critical control point to control pathogen survival in cooked, ready-to-eat, Dungeness Crabmeat did not contain the actual temperatures observed during monitoring.

During the previous inspection, on April 22-23, 1999, and in a letter from the FDA, dated May 19, 1999, you were notified of the same deficiencies described in point number one of this letter. During the inspection, and in the letter, the FDA explained that you would need to take steps to correct those deficiencies. The FDA is concerned that in five months time your firm has not taken action to correct these deficiencies.

The above HACCP violations are not meant to be an all-inclusive list of deficiencies in your plant. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your revised HACCP plan and copies of your monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations. Pertinent sections of the Act and regulations are enclosed for your review.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have any questions regarding any issue in this letter, please contact Lisa Elrand at (425) 483-4913.

Sincerely,

Charles M. Breen
District Director

Enclosures:
Form FDA 483
21 CFR Part 123
Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: With Disclosure Statement
WSDA